EXHIBIT 53

Patent
Attorney's Docket No. 22338-10230, -10231

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Control Nos.:	**90/007,542** **90/007,859**	Group Art Unit:	3991
Confirmation Nos.:	7585 ('542) 6447 ('859)	Examiner:	B.M. Celsa
Filed:	13 May 2005 ('542) 23 December 2005 ('859)		
Patent Owner:	Genentech, Inc. and City of Hope		

For: Merged Reexaminations of U.S. Patent No. 6,331,415 (Cabilly et al.)

DECLARATION OF DR. E. FINTAN WALTON UNDER 37 C.F.R. § 1.132

I, E. Fintan Walton, do hereby declare and state

1. I am a citizen of and reside in the United Kingdom.

2. I hold bachelor's and doctoral degrees, both from Trinity College, University of Dublin, Ireland. I also conducted research at the University of Michigan. My research experience, in which I reached the level of departmental head at Celltech Ltd. (1984-1992), covered gene expression, metalloproteinases and HIV research. I gained broad commercial experience in biotechnology in my management positions at Celltech Ltd. (1984-1992), and before that at Bass Brewing Ltd. (1982-1983).

3. I am presently Chairman and CEO of PharmaVentures Ltd., a company that assists healthcare company clients in forming alliances, conducting acquisitions and executing other transactions of strategic importance, including patent license agreements. In addition to its consulting services, PharmaVentures publishes reports on deal making to the pharmaceutical and related industries and produces a proprietary comprehensive database, PharmaDeals, which contains details of over 28,000 transactions that have taken place in the pharmaceutical industry. Those details include, where available, information on total deal value, upfront payments, equity investments, milestone payments, royalty rates and other financial parameters.

4. Through my experience at PharmaVentures and elsewhere, I have built up substantial expertise in the analysis of healthcare markets and of pharmaceutical and biotechnology

companies, their technologies, and their intellectual property. Deal structuring, valuation and negotiation form a major part of my business.

5. My company has been retained for this reexamination to evaluate certain conclusions made by the Patent and Trademark Office about the licensing of U.S. Patent 4,399,216 (the "Axel patent") as reported in an article published in the Harvard Journal of Law & Technology Vol. 17, No. 2, Spring 2004, at pp. 583-618 (the "Harvard Journal article"). We were also asked to evaluate the licensing of U.S. Patent No. 6,331,415 ("the '415 patent") to determine if the '415 patent is recognised within the industry and enjoys commercial success that would be relevant to the patentability of the '415 patent.

6. My company has been previously retained to act as an expert witness in MedImmune, Inc. v. Genentech, Inc. and City of Hope, Case No. CV03-2567, which was filed in the Central District of California.

7. I note that I have been, and am being, compensated for my time at a rate of $650.00 per hour. Attached as Exhibit A is a list enumerating the materials that I reviewed in preparing my declaration.

Introductory Remarks

8. I have extensive experience in reviewing patent licensing practices in the healthcare sector. I have reviewed many patent license agreements and evaluated the circumstances under which these licenses were taken.

9. Based on my experience, I have learned that in executing a patent license, a company usually will not agree to pay substantial fees, or provide other significant economic concessions, to a patent owner unless that company has reached a conclusion that the patentee could successfully enforce the patent being licensed against the company. If the prospective licensee reaches a conclusion that either the patent is invalid, or that its conduct would not result in a finding of infringement of the patent, that prospective licensee generally will not take the license, or will not otherwise provide any significant economic concessions to the patent owner.

Observations On Overlap of Axel Licensees and '415 Patent Licensees

10. I have read the comments at page 46 of the Final Action concerning the licensing of the Axel patent, based on what was reported in the Harvard Journal article. In particular, I observe that the Final Action concludes from what is reported in the article that the licensing of the Axel patent provides evidence that "one of ordinary skill in the art interpreted the *Axel patent* claims as being directed to functional proteins, including antibodies." I do not draw the same conclusion from this article.

11. Initially, I observe that the Harvard Journal article describes the technological advance made by Dr. Axel and his collaborators as being the simultaneous transformation of a eukaryotic cell with a selectable marker and another foreign gene that coded for desired proteinaceous material, where the presence of the selectable marker allowed for isolation of successful transformants from non-transformants (see generally pp. 584-586).

12. The Harvard Journal article does not explain why the reported Axel patent licensees took a license under one or more of the Axel patents. It does provide, at pages 592-593, a list of observations based on the reported Axel patent licenses.

13. According to the Harvard Journal article, six of the products reported as subject to a license under the Axel patent do not fall within any of the categories specifically claimed in that patent.[1] See Harvard Journal article at pp. 592-593. These products include: Ovidrel®, a recombinant human chorionic gonadotropin; Epogen® and Procrit®, recombinant human erythropoietin; Aranesp®, a modified recombinant human erythropoietin; Gonal-f®, a human follicle stimulating hormone; and Thyrogen®, a recombinant human thyroid stimulating hormone. See Harvard Journal article at pp. 615, 616 and 618.

14. The Harvard Journal article also indicates that the majority of the reported licensed products, including certain Genentech products, are not antibodies. See Harvard Journal article at pp. 592-593, 614-618.

15. The Harvard Journal article reports that 28 of 29 of the products reported as subject to a license under the Axel patent are produced in CHO cells (a particular type of mammalian host cell), and that "...it is almost certain that all [of the manufacturing processes] use some selective agents in culturing their transformed cells in accordance with the Axel patent." Harvard Journal article at p. 593.

16. In view of these observations, I do not believe one can reasonably conclude that companies took licenses under the Axel patent based on an understanding that the licensed product was specifically claimed in the Axel patent. Indeed, at least six of the products are not specifically claimed in the Axel patent. This demonstrates to me that whether the protein made by these licensees was specifically claimed in the Axel patent could not have been a significant reason why they took their respective licenses.

17. To the extent that one can infer anything from what is reported in the Harvard Journal article about why the Axel patent licensees took their respective licenses, it would be that these licensees believed the Axel patent to be broadly claiming the technique of using a selectable marker in mammalian host cells that allowed for isolation of successful transformants from non-transformants. This seems to be the only common factor reported in the licensing data for the licensed products. It is also the advance in the field of recombinant DNA technology that the Harvard Journal article attributes to Dr. Axel and his collaborators.

18. Accordingly, I do not believe the licensing information provided in the Harvard Journal article is evidence that a person of ordinary skill in the art interpreted the Axel patent claims as being directed to production of functional proteins, including antibodies.

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[1] The Axel patent claims indicate that the foreign DNA employed could code for interferon, insulin, growth hormone, clotting factor, viral antigen, antibody or enzyme. See Harvard Journal article at page 588 and Axel patent claims 3-8.

19. An additional observation can be made about the licensing experiences of the Axel patent. Specifically, I observe that two antibody products were identified in the Harvard Journal article as having been licensed under the Axel patent (i.e., Humira® by Abbott, and Zevalin® by Biogen Idec). See Harvard Journal article at pp. 614, 617. These two antibody products are also licensed under the '415 patent.[2]

20. I believe Abbott and Biogen Idec are companies with extensive experience in licensing patents concerning biological products. Based on my experience, the decision of each company to license both the '415 and Axel patents suggests two things. First, each company must have concluded that both patents covered in some manner the way their products are made. Second, each company must have concluded that the '415 patent was independently patentable over the Axel patent. Otherwise, neither company would have taken a license under both patents, or paid royalties under both patents to different patent owners.

Overview of the '415 Patent, and Its Place in the Industry and Market

21. I have been informed that evidence of substantial licensing of an invention by market participants supports a conclusion that the invention is not obvious, in part because it indicates that the industry has recognised that the patent represents a non-obvious advance over the prior art. I also have been told that evidence of commercial success of an invention supports a conclusion that an invention is not obvious over the prior art.

22. I understand that evidence of licensing and commercial success of the '415 patent is appropriate to consider if it can be linked to the merits of the invention (e.g., as opposed to being attributable to the prior art). In this case, this means that licensing and commercial success evidence is relevant if it can be shown to be attributable to the merits of the '415 patent, rather than being due to the merits of U.S. Patent 4,816,567 ("the '567 patent") and other prior art, or being due to other factors unrelated to the merits of the '415 patent.

23. Accordingly, I have evaluated whether the licensing by others of the '415 patent, and the royalties Genentech has been paid on U.S. sales of products licensed under the '415 patent, are properly attributable to the merits of the '415 patent, independent of the merits of the '567 patent and other prior art.

Licensing Activity of the '415 Patent

24. I have reviewed each of the licenses Genentech has entered into under the '415 patent.[3] In general, confidentiality considerations between Genentech and the licensees preclude

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[2] I know this based on my review of each of the licenses Genentech has entered into under the '415 patent.

[3] Because of confidentiality considerations regarding these licenses, I have not provided a detailed table of the companies, products, and terms of the licenses. Nevertheless, my opinions are grounded on the terms of these licenses.

public disclosure of many terms and conditions of the licenses. Because of this, I present my findings in a manner that limits disclosure of license terms.

25. Genentech has licensed the '415 patent, either in conjunction with the '567 patent or without the '567 patent, to at least 35 companies.

26. Of the companies that have licensed the '415 patent, many have elected to take licenses under both the '567 and the '415 patents, while others have taken licenses only under the '415 patent[4] and not under the '567 patent.

27. A number of licenses granting rights under both the '567 and '415 patents require the licensee to pay one royalty on net sales of products covered by the '567 patent and a separate and additional royalty on net sales of products covered by the '415 patent, even if the product was also covered by the '567 patent. In other words, in certain of these "dual" licenses, the royalty obligations under each patent are independent.[5]

28. I also observe from my review of the licenses that after the '415 patent issued, but before the '567 patent expired, several licenses were entered into that granted rights only under the '415 patent (i.e., without also granting rights under the '567 patent).

29. A number of the companies that have taken a license under the '415 patent are currently marketing an antibody product under that license within the United States.[6]

30. The companies that have taken licenses under the '415 patent include some of the largest biotechnology and pharmaceutical companies in the world in terms of product revenue, as identified by Med Ad News in 2005 and 2007.[7]

Revenue Generated From Licensing Activity

31. I have reviewed reports of royalty payments made by licensees under the '567 and the '415 patents for therapeutic antibody products sold in the U.S., including a compilation of

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[4] These licenses did grant rights to continuations, continuations-in-part, divisionals of the '415 patent, and foreign counterparts of those patents. No such U.S. patents have issued to date.

[5] MedImmune has licensed both the '415 and the '567 patent for Synagis®, but has paid royalties to Genentech only under the '415 patent. *See* Joint Appendix Volume 1 filed with the United States Supreme Court in *MedImmune, Inc. v Genentech*, No. 05-608 at pp. 414-416.

[6] Some products publicly known to be licensed under the '415 patent are Humira®, Remicade®, Synagis®, Tysabri® and Erbitux®. *See* Genentech Presentation by David Ebersman, Investment Community Meeting, Financial Overview, 14 March 2008, at slide 8, available at, www.gene.com/gene/ir/webcasts/pdf/finance.pdf.

[7] Med Ad News, July 2005, "Top 100 biotechnology companies;" Med Ad News, September 2007, "Top 50 pharmaceutical companies."

this data prepared by employees of Genentech in the finance group.[8] That compilation provides data showing royalty payments made on U.S. sales of antibody products licensed under the '415 patent that Genentech has received on an annual basis since its issuance.

32. I have discussed the information that I received from Genentech and the manner in which the information was generated with the employees in the finance group who compiled this information. In particular, I have been informed that the information was compiled from royalty statements that licensees of the '415 patent provided to Genentech for sales made during the quarter covered by the licensee's royalty statement. I have also been informed that those statements differentiated sales made in the U.S. from sales made outside of the U.S.

33. Because I understand how the information was collected and have reviewed the licensing provisions that correspond to these royalty payments, I believe the data I reviewed accurately reflect the royalties that Genentech has been paid pursuant to licenses under the '415 patent, whether or not in conjunction with the '567 patent.

34. I believe it is possible to readily identify a portion of the total licensing revenue, paid to Genentech by all licensees of either or both of the '415 and '567 patents, that is exclusively attributable to the '415 patent. Specifically, this would be amounts of licensing revenue paid by: (a) companies that have licensed only the '415 patent, and not the '567 patent; and (b) MedImmune for license obligations arising from sales of Synagis®, which MedImmune asserts it pays only because of its obligation under the '415 patent.[9] As of December 31, 2007, these amounts totaled approximately $346 million.

35. I note that this estimate is conservative because I have not included any amounts of royalty payments made by dual licensees, other than MedImmune, under the '415 and '567 patents. I note that a portion of such royalties would certainly be exclusively attributable to '415 patent license obligations because many of the license provisions impose independent obligations on the licensee to pay royalties on each of the '415 and '567 patents.

36. In 2007, there were 21 therapeutic antibodies or therapeutic products containing an antibody fragment (collectively "therapeutic antibody products") marketed within the U.S. These products are identified in Table 1 of Piggee, Christine, "Therapeutic Antibodies Coming Through the Pipeline," Analytical Chemistry, Vol. 80 Issue 7, pp. 2305-2310 (April 2008), along with other antibody related drugs, including *in vivo* diagnostic agents. These products are used in treating cancer, inflammation, allergy, organ transplant rejection, macular degeneration as well as cardiovascular, autoimmune and infectious diseases. Based on my review of the '415 licenses that Genentech has

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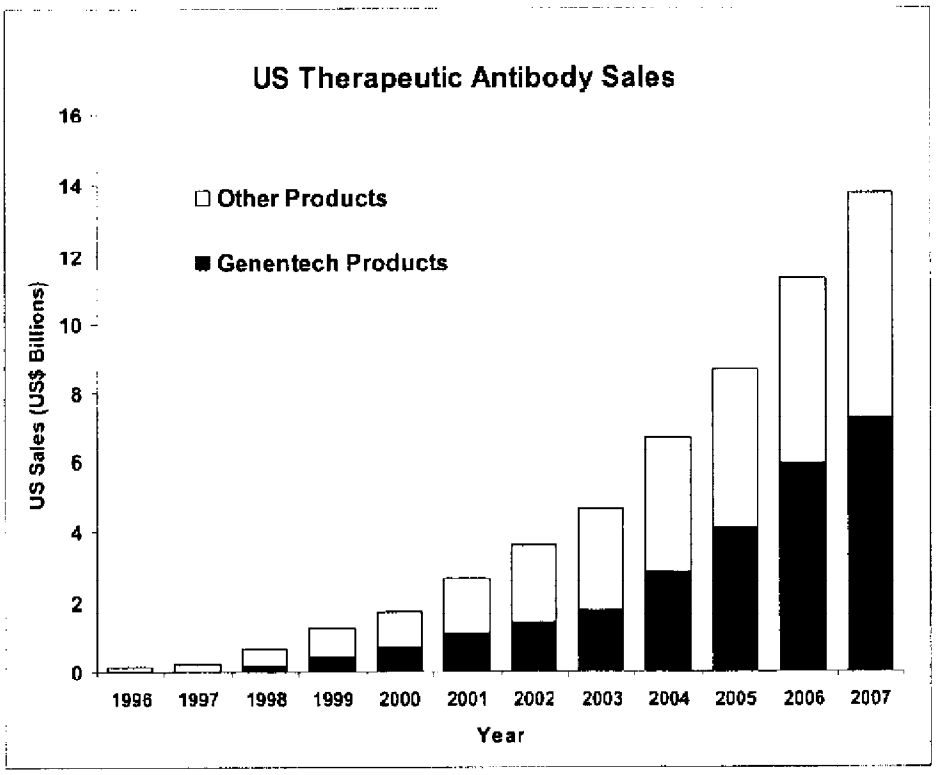
[8] Because of confidentiality considerations concerning these licenses, I cannot provide this compilation as an appendix to this declaration. However, I can and do report information from this compilation in a way that reasonably respects these confidentiality considerations.

[9] See footnote 5.

entered into, almost all of the 21 therapeutic antibodies identified in the Piggee article are licensed under the '415 patent, both alone and in conjunction with the '567 patent. As illustrated in the figure below, the yearly U.S. sales of all of the 21 therapeutic antibody products have been significant and show a strong positive trend. Based on the licenses that I have reviewed and the information reviewed to generate this figure, I am aware that billions of dollars of the U.S. sales of non-Genentech products are attributable to products licensed under the '415 patent.



Source: EvaluatePharma

Conclusions Regarding Recognition of Others

37. Dozens of pharmaceutical companies, including some of the largest in the world in terms of product revenues, have licensed the '415 patent. A subset of these companies markets many of the 21 therapeutic antibodies that are presently available on the U.S. market and have paid substantial sums for the right to practice the '415 patent technology.[10]

[10] As noted above, in addition to the $346 million that is readily attributable exclusively to the '415 patent, there is a portion of royalties paid by dual licensees that would certainly be exclusively attributable to '415 patent license obligations because many of the license provisions impose independent obligations on the licensee to pay royalties on each of the '415 and '567 patents.

38. Based on my experience, it is reasonable to conclude that licensees of the '415 patent took a license under that patent after assessing its validity and whether their conduct could be found to infringe the patent. In my opinion, one part of the validity assessment would have been whether the '415 patent defined a patentable invention over the '567 patent claims, considered with any other information in the public record prior to the filing date of the two patents.

39. For any licensee agreeing to pay separate royalties on both the '415 and the '567 patents in the event the licensed product was believed to implicate both patents, the licensee would have had an additional motivation to focus on whether the '415 patent defined inventions that were separately patentable over the '567 patent claims.

40. The fact that so many companies have licensed the '415 patent, and that a subset of those companies have paid substantial sums to Genentech attributable solely to the licensing of the '415 patented technology, indicates to me that there is widespread industry recognition that the '415 patent claims are independently patentable over the '567 patent claims and the prior knowledge concerning antibody technology.

41. I also believe that the evidence showing that commercially marketed therapeutic antibodies have been licensed under only the '415 patent indicates that the companies that took these '415-only licenses believed that the '415 patent defined a distinct and separately patentable invention relative to the '567 patent claims when they took those licenses.

42. Based on my experience, the '415 patent is one of a relatively small number of patents that have been broadly licensed to many companies in the biotechnology industry.

43. As I understand the role licensing of the patent plays in obviousness evaluations, I believe the foregoing strongly supports a conclusion that the '415 patent claims define inventions that are not obvious over, and therefore independently patentable in view of, the '567 patent claims, when they are considered alone or in conjunction with the prior art known before the common filing date of these patents.

Conclusions Regarding Commercial Success

44. As explained in paragraph 36 above, the therapeutic antibody products that are licensed under the '415 patent have generated billions of dollars in drug sales. These monoclonal antibodies are sold for use in numerous therapeutic fields.

45. Genentech has received several hundred million dollars in royalties from these companies that are attributable solely to licenses granted under the '415 patent. I believe, based on my experience, that these companies paid these substantial royalties because they have each concluded that the way they make their products would likely be found by a court to be covered by the '415 patent claims. In my opinion, this is strong evidence of a substantial degree of commercial success that is attributable solely to the '415 patent.

46. As I understand the role that this evidence plays in obviousness evaluations, I believe these significant amounts of compensation that companies have paid Genentech pursuant

to their license obligations is evidence of commercial success of the '415 patent, and supports a conclusion that the '415 patent claims are not obvious over the '567 patent claims, when they are considered alone or in conjunction with the other prior art known prior to the common filing date of the '567 patent.

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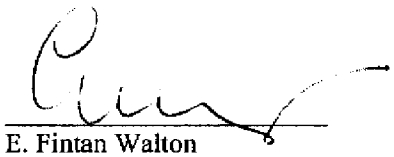
I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardise the validity of the patent subject to this reexamination proceeding.



E. Fintan Walton

4 June 2008

Date

EXHIBIT A

List of Materials Reviewed In Preparing this Declaration:

U.S. Patent and Trademark Office's communication dated February 25, 2008
Recent Developments "Columbia, Co-transformation, Commercialization & Controversy: The Axel Patent Litigation," Harvard Journal of Law & Technology, Vol. 17, No. 2, Spring 2004 pp. 583-618
U.S. Patent No. 4,399,216
U.S. Patent No. 6,331,415
U.S. Patent No. 4,816,567
Genentech-Cabilly License agreements produced under the protective order in MedImmune, Inc. v. Genentech, Inc. and City of Hope, Case No. CV03-2567
Genentech Royalty Statements regarding '415 and '567 patents produced under the protective order in MedImmune, Inc. v. Genentech, Inc. and City of Hope, Case No. CV03-2567
Joint Appendix Volume 1 filed with the United States Supreme Court in MedImmune, Inc. v Genentech, No. 05-608
Genentech Presentation by David Ebersman, Investment Community Meeting, Financial Overview, 14 March 2008, at slide 8, available at, www.gene.com/gene/ir/webcasts/pdf/finance.pdf
Summary Report of Royalties Paid to Genentech by licensees of the '415 patent, prepared by Genentech based on information sent by licensees of the '415 patent to Genentech
Med Ad News, July 2005, "Top 100 biotechnology companies"
Med Ad News, September 2007, "Top 50 pharmaceutical companies"
Piggee, Christine "Therapeutic Antibodies Coming Through the Pipeline," Analytical Chemistry, Vol. 80, Issue 7, pp. 2305-10. (April 2008)
EvaluatePharma, (analysis and intelligence service for the pharma and biotech sector), London, UK